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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,114	08/18/1998	IAN ASHLEY PRICE	P8129-8004	7439

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EXAMINER	
JIANG, SHAOJIA A	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/125,114	PRICE, IAN ASHLEY	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-15,20-25,32-37 and 39-73* is/are pending in the application.

4a) Of the above claim(s) *11-15,20-25,32-37 and 48-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-47 and 52-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 27, 2005 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed April 27, 2005, and amendment and response to the Final Office Action (mailed January 27, 2005), filed April 27, 2005 wherein claims 39-47 and 52-53 have been amended; claims 54-73 are newly added. Claims 1-10, 16-19, 26-31 and 38 are cancelled previously.

Currently, claims 11-15, 20-25, 32-37 and 39-73 are pending in this application.

It is noted that Claims 11-15, 20-25, 32-37 and 48-51 are withdrawn from further consideration pursuant to 37 CFR 1 .142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse recorded in the previous Office Action October 18, 2002.

Claims 39-47 and 52-73 are examined on the merits herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 39-47 and 52-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armitage et al. (WO 9220334 of record) in view of Gregory et al. (5,262,179 of record).

Armitage et al. disclose a pharmaceutical composition comprising ibuprofen salt in racemic mixture of S-ibuprofen, such as alkaline earth metal salts, for example the sodium salt of ibuprofen (see page 1 lines 8-22, page 2 lines 1-5), and a carrier, a compressible filler component such as lactose, microcrystalline, and calcium phosphate (see page 5 lines 33 to page 6), combined with a disintegrating component such as maize starch and lubricating agents (see page 5 lines 4-15). Armitage et al. also disclose the effective amounts of ingredients therein, such as preferably, a solid composition comprises a) 10-99% of ibuprofen or a doses for example 100 mg, 200mg, 400mg, or 800mg of ibuprofen; b) 1-90% of a filler or diluent, c) 0.1-10% of a lubricating agent (disintegrating component) and other ingredients, see page 5 lines 1-3 and 27-32.

In particular Armitage et al. disclose that the ibuprofen pharmaceutical composition tablets are coated with enteric coatings (also including a known film-coated) (see page 6 lines 20-37), and hydroxypropylmethyl cellulose or polysaccharide is employed therein (see page 6 lines 36-37). Note that Applicant also clearly

acknowledges and admits concerning coating formulations, that "[i]n such formulations the remaining layers or core may comprise standard excipients to provide conventional, fast or slow release and are well within the knowledge of a person skilled in the art (eg. see Remington's Pharmaceutical Sciences, 17th Edition, Ed Gennaro et al)." (see page 16 lines 4-14 of the specification herein).

The cited prior art does not expressly disclose the employment of the particular sodium carbonate or sodium bicarbonate 3-20% by weight in the ibuprofen dosage of Armitage et al. and the particular amount sodium salt of ibuprofen may be 40-60%.

Gregory et al. discloses that ibuprofen salts have an unpleasant taste and, therefore, it is advantageous to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form (see abstract), especially sodium bicarbonate, e.g., in 10% or 26.9% by weight, and ibuprofen in 15.5% 16%, 19.7% or 20% by weight, and the various weight ratio of sodium bicarbonate to ibuprofen is also disclosed (see col.2 lines 27-30, the particular compositions comprising the instant ingredients with specific amounts within the instant claimed, see Example 1-20 of col.4-10), For the sodium salt of ibuprofen, see col. 3, lines 26-30.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular sodium carbonate or sodium bicarbonate in 3-20% by weight in the ibuprofen dosage of Armitage et al. and to optimize the amount of sodium salt of ibuprofen may be 40-60% in the compositions of the prior art cited.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular sodium carbonate or sodium bicarbonate

3-20% by weight in the ibuprofen dosage of Armitage et al. because it is known that ibuprofen salts have an unpleasant taste and, therefore, it is advantageous to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form especially sodium bicarbonate according to Gregory et al. The instant effective amounts or ratio of sodium bicarbonate and ibuprofen are also known according to Gregory et al.

Note that the cited prior does not disclose the inherent properties of the composition such as crushing strength, disintegration time or compression force as instantly claimed. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical or similar compositions, the properties Applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

Claims 39-47 and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Geyer et al. (5,380,535) in view of Gregory et al. (5,262,179) for same reasons of record stated in the Office Action dated May 19, 2004.

Geyer et al. discloses chewable compositions for oral delivery of unpalatable

drugs (abstract). Chewable products in the form of compressed tablets (claim 10) or uncompressed powder (see column 2, lines 37-39). The composition therein comprises an unpalatable drug, a lipid and various other conventional excipients and additives. For mannitol and lactose, see column 6, lines 2-6. For microcrystalline cellulose, see column 7, lines 26-28. These are Applicants preferred compressible fillers of instant claims 8 and 31. For sodium bicarbonate, see column 6, lines 16-28. For sodium starch glycolate, croscarmellose sodium and cross-linked polyvinylpyrrolidone (crospovidone), the disintegrating components of instant claims 9 and 30, see column 6, lines 42-68.

A compressed tablet also comprising lubricants and flow aids is disclosed at Column 7, lines 20-30. An ibuprofen composition comprising 0.5-40 wt.% ibuprofen, 25-75 wt. % granulating agent (mannitol and lactose compressible fillers), 1-30 wt.% dispersal agent (sodium starch glycolate and croscarmellose sodium) and 0.5-7 wt.% lubricant is disclosed at column 8, lines 1-36. US 535 0.2-10 wt.% of inert diluents such as flavorants and sweeteners (col. 8, lines 20-30). See also Examples 3 and 5 and claims 3 and 17 for ibuprofen, sodium bicarbonate, compressed tablets and mannitol.

Geyer et al. discloses a powder that can be compressed into a tablet comprising ibuprofen, a compressible filler, a disintegrant, sodium bicarbonate, lubricants and flow aids.

In particular Geyer et al. disclose that the ibuprofen pharmaceutical compositions therein can be tableted, coated, encapsulated by methods known in the pharmaceutical art (see col. 3 line 67 to col.4 line 2), as Applicant also clearly acknowledges and admits

concerning coating formulations, that "[i]n such formulations the remaining layers or core may comprise standard excipients to provide conventional, fast or slow release and are well within the knowledge of a person skilled in the art (eg. see Remington's Pharmaceutical Sciences, 17th Edition, Ed Gennaro et al)." (see page 16 lines 4-14 of the specification herein).

Geyer et al. does not disclose the crushing strength, disintegration time or compression force as instantly claimed, a salt of ibuprofen or a solid formulation having a layer as instantly claimed and the cited prior art does not expressly disclose the employment of the particular sodium carbonate or sodium bicarbonate in 3-20% by weight in the ibuprofen dosage of Geyer et al. and the particular amount sodium salt of ibuprofen may be 40-60%.

Gregory et al. discloses that ibuprofen salts have an unpleasant taste and, therefore, it is advantageous to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form (see abstract), especially sodium bicarbonate, e.g., in 10% or 26.9% by weight, and ibuprofen in 15.5% 16%, 19.7% or 20% by weight, and the various weight ratio of sodium bicarbonate to ibuprofen is also disclosed (see col.2 lines 27-30, the particular compositions comprising the instant ingredients with specific amounts within the instant claimed at Example 1-20 of col.4-10), For the sodium salt of ibuprofen, see col 3, lines 26-30.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular sodium carbonate or sodium bicarbonate in the amount herein and 3-20% by weight in the ibuprofen dosage of Geyer et al. and to

optimize the amount of sodium salt of ibuprofen may be 40-60% in the compositions of the prior art cited.

One of ordinary skill in the art would expect a composition containing the same components to exhibit similar properties. Additionally, it is considered within the skill in the art to select optimal parameters in order to obtain beneficial effects. The recitation of the compression force leads the claim to a product-by-process claim. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The prior ad teaches dosage forms containing the same components as instantly claimed. Therefore, absent evidence of unexpected results, the crushing strength, disintegration time and compression force are not considered critical to the invention.

Further, one having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular sodium carbonate or sodium bicarbonate 3-20% by weight in the ibuprofen dosage of Geyer et al. because it is known that ibuprofen salts have an unpleasant taste and, therefore, it is advantageous to provide a dosage form that masks the taste of ibuprofen by incorporating an alkali metal bicarbonate into the dosage form especially sodium bicarbonate according to Gregory et al. The instant effective amounts or ratio of sodium bicarbonate and

ibuprofen are also known according to Gregory et al. Thus, a *prima facie* case of obviousness exists.

Response to Argument

Applicant's arguments filed April 27, 2005 with respect to the rejection of claims 39-47 and 52-53 made under 35 U.S.C. 103(a) as being unpatentable over Geyer et al. (5,380,535) in view of Gregory et al. (5,262,179) record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicants argue that "the reference does not disclose the crushing strength, disintegration time or compression force as instantly claimed, a salt of ibuprofen or a solid formulation having a layer as instantly claimed". Applicants also assert the difference between the compressed dosage form claimed herein and the one disclosed by Geyer et al.

Applicants argument is not found convincing. The examiner notes in the previous Office Action that Geyer et al. (5,380,535) does not expressly disclose these limitations: the crushing strength, disintegration time or compression force, a salt of ibuprofen or a solid formulation having a layer. However, Geyer et al. discloses a compressed ibuprofen tablet. Moreover, the previous Office Action clearly states:

> "the cited prior does not disclose the inherent properties of the composition such as crushing strength, disintegration time or compression force as instantly claimed. Any properties exhibited by or benefits provided the composition are inherent and are not given patentable weight over the prior art. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical or similar compositions, the properties Applicant discloses and/or

claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product."

Thus, the burden is shifted to Applicant to show that the prior art product does not inherently possess the same properties as instantly claimed product, in order to rebut this rejection.

Note that arguments of counsel cannot take the place of factually supported objective evidence. See, e.g., In re Huang, 100 F.3d 135,139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); In re De Blauwe, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

Applicant's arguments filed April 27, 2005 with respect to the rejection of claims 39-47 and 52-53 made under 35 U.S.C. 103(a) as being unpatentable over Armitage et al. (WO 9220334) in view of Gregory et al. (5,262,179) of record in the previous Office Action have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicants assert that "Armitage et al. aims to solve a completely different problem than Gregory et al. and also from the problem addressed by the invention of the present application". Contrary to Applicants' assertion, both the inventions of Armitage et al. and Gregory et al. are directed to the ibuprofen salt compositions. Moreover, the teaching of Gregory et al. is deemed to provide the motivation for using the sodium salts for masking the taste of such salts.

Further, note that the court rejects the idea that the prior art must suggest the combination of elements for the same reason as the applicant. See *In re Dillon* 919 F. 2d 688, 16 USPQ2d 1897 (Fed Cir. 1990).

Applicants also argue that "Gregory et al. is directed to taste masking aqueous solutions of water soluble ibuprofen salts in aqueous solution. For solid dosage forms which are swallowed whole, taste masking considerations (i.e. Gregory) do not come into play". Applicants' argument is not persuasive. Even though solid dosage forms which are swallowed whole, taste masking considerations indeed still come into play for simple reasons. First a human mouth is wet with aqueous solution, not 100% dry; second, solid dosage forms are swallowed whole that needs to accompany with aqueous solution, e.g., water.

Therefore, motivation provided by the combined teachings of the prior art herein to make the present invention is clearly present. The claimed invention is clearly obvious in view of the prior art.

Applicant's Examples of the specification at pages 20-31 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art. In this regard, it is noted that the specification provides no side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art.

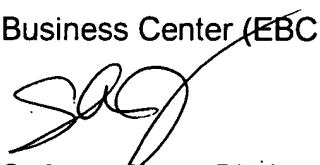
For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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June 17, 2005